

The opinion in support of the decision being entered today was **not** written for publication and is **not** binding precedent of the Board.

Paper No. 23

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE BOARD OF PATENT APPEALS  
AND INTERFERENCES

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*Ex parte* DOMENICO FANARA, MONIQUE BERWAER,  
ANNE BOUQUELLE, and MICHEL DELEERS

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Appeal No. 2003-0569  
Application No. 09/381,044

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ON BRIEF

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Before TIMM, ADAMS, and GRIMES, *Administrative Patent Judges*.  
TIMM, *Administrative Patent Judge*.

***DECISION ON APPEAL***

Appellants appeal the final rejection of claims 11-20, all the claims pending in the Application.<sup>1</sup> We have jurisdiction under 35 U.S.C. § 134.

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<sup>1</sup>The two After-Final Amendments (Paper Nos. 12 and 16) were not entered (Advisory Action, Paper No. 13; Office Communication, Paper No. 21) and, thus, the claims proposed therein will not be considered in our review.

### ***INTRODUCTION***

Claim 11 is illustrative of the subject matter on appeal:

11. A pharmaceutical composition which can be administered orally, allowing the controlled release of at least one active substance, comprising:

a) the said at least one active substance,

b) between 5 and 60% by weight, relative to the total weight of the composition, of at least one excipient, selected from the group consisting of inert matrices, hydrophilic matrices, lipid matrices, mixtures of inert matrices and of lipid matrices, and mixtures of hydrophilic matrices and of inert matrices, with the exception of mixtures comprising a polyacrylic acid and at least one hydrophilic matrix of the cellulose type; and

c) between 5 and 50% by weight, relative to the total weight of the composition, of at least one alkalinizing agent soluble in an aqueous phase under physiological pH conditions, selected from the group consisting of alkali or alkaline-earth metal hydroxides, carbonates, bicarbonates, phosphates, sodium borate and basic salts of organic acids.

Claims 11-20 stand rejected under 35 U.S.C. § 103(a). As evidence of obviousness, the Examiner relies upon the following prior art references:

Kwan et al. (Kwan) (PCT)	WO 94/09761	May 11, 1994
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Norling et al. (Norling) (PCT)	WO 95/34291	Dec. 21, 1995
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The Examiner rejects all the claims as obvious over Norling alone or Norling in view of Kwan.

We reverse for the following reasons.

***OPINION***

All of the claims require the presence of at least one excipient selected from a group of various matrices including hydrophilic matrices. The specification identifies hydroxypropyl methyl cellulose as a usable hydrophilic matrix material (specification, p. 4, ll. 22-23). The rejections over Norling alone and Norling in view of Kwan are based on the fact that Norling suggests compositions including hydroxypropyl methyl cellulose as a binding agent (Answer, p. 4). The Examiner equates the binder of Norling with the required matrix excipient of the claims.

Appellants argue that there is a difference between a matrix excipient and a binder and cite the fact that Appellants' specification lists binders as separate optional ingredients as evidence of this. According to Appellants, matrices form an extended network within which the active ingredient is slowly released whereas a binder is present in smaller amounts and acts simply to hold the ingredients together (Brief, p. 6).

The Examiner argues in response that Appellants have provided no evidence to support the contention that binders are present in smaller amounts. The Examiner also states that hydroxypropyl methyl cellulose is well known in the pharmaceutical art as a matrix excipient, and absent evidence to the contrary, the hydroxypropyl methyl cellulose would perform the same function whether included as a matrix excipient or a binder (Answer, p. 7).

The Examiner provides no technical reasoning nor evidence indicating that use of hydroxypropyl methyl cellulose as a binding agent inherently results in a matrix or that use as a binder would have suggested use as a matrix. On the other hand, the fact that Appellants'

specification lists matrices separately from binders provides some evidence that the two are structurally different and that the suggestion of one would not have suggested the other to one of ordinary skill in the art.

The ordinary and accustomed meaning of “binder” and “matrix” also supports Appellants’ argument. A binder produces or promotes cohesion in loosely assembled substances.<sup>2</sup> A matrix is a material in which something is enclosed or embedded.<sup>3</sup> Something that promotes cohesion need not form a matrix. The word matrix suggests a network structure and such a network structure is more continuous in extent than the less continuous distribution needed to merely cause cohesion.

While the Examiner argues that Appellants have not provided evidence of a difference, the burden is on the Examiner to provide factual support for the *prima facie* case of obviousness. *In re Oetiker*, 977 F.2d 1443, 1445, 24 USPQ2d 1443, 1444 (Fed. Cir. 1992). We note that Norling is relied upon in both rejections as teaching the required excipient and, therefore, as applied by the Examiner, Kwan does not remedy the deficiencies in the *prima facie* case. We conclude that the Examiner has not established a *prima facie* case of obviousness with respect to the subject matter of claims 11-20.

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<sup>2</sup>See Binder, *Merriam-Webster Collegiate Dictionary*, electronic version 2.5 (2000) at definition 3. A copy accompanies this Decision.

<sup>3</sup>See Matrix, *Merriam-Webster Collegiate Dictionary*, electronic version 2.5 (2000) at definition 3b. A copy accompanies this Decision.

***CONCLUSION***

To summarize, the decision of the Examiner to reject claims 11-20 under 35 U.S.C.  
§ 103(a) is reversed.

REVERSED

CATHERINE TIMM	)	
Administrative Patent Judge	)	
	)	
	)	
	)	
	)	BOARD OF PATENT
DONALD E. ADAMS	)	APPEALS
Administrative Patent Judge	)	AND
	)	INTERFERENCES
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ERIC GRIMES	)	
Administrative Patent Judge	)	

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